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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,118	02/26/2002	G. Scott Herron	464362000320	2762

7590 08/22/2003
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Morrison & Foerster LLP
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EXAMINER

CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 08/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/086,118

Applicant(s)

HERRON, G. SCOTT

Examiner

Shin-Lin Chen

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-16, 26, 28-32, 34 and 36, drawn to a composition of endothelial cells comprising immortal microvascular endothelial cells comprising a expression cassette encoding telomerase in vitro, and a method of making said composition in vitro, classifiable in classes 424 and 435, subclasses 93.21 and 373.
 - II. Claims 17-25 and 27-40, drawn to a composition of endothelial cells comprising immortal microvascular endothelial cells comprising a expression cassette encoding telomerase in vivo, and a method of making said composition in vivo, classifiable in classes 424 and 435, subclasses 93.21 and 373.
 - III. Claims 41 and 42, drawn to a method that demonstrates neovasculture formed in vivo by using genetic marker detectable by a digital imaging system, classified in class 435, subclass 4.
 - IV. Claims 43 and 44, drawn to an isolated graft comprising the cells of claim 1 and a method of treating atherosclerosis by implanting said graft, classified in class 435, subclass 1.1.
 - V. Claims 43 and 45, drawn to an isolated graft comprising the cells of claim 1 and a method of treating tumors by implanting said graft, classified in class 435, subclass 1.1.
 - VI. Claims 43 and 46, drawn to an isolated graft comprising the cells of claim 1 and a method of enhancing wound healing by implanting said graft, classified in class 435, subclass 1.1.

Claims 28-32, 34 and 36 link(s) inventions I and II. Claim 43 links inventions IV-VI.

The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 28-32, 34, 36 and 43. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MEP. § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are distinct from each other because they are drawn to different scientific considerations: group I is directed to a composition of endothelial cells, forming microvascular structures in vitro and a method making said composition in vitro, however, group II is directed to a composition of endothelial cells, forming microvascular structures in vivo and a method making said composition in vivo. The in vitro and in vivo microenvironments differ dramatically from each other where the in vitro environment is well controlled but the in vivo environment has numerous unpredictable factors that can affect making of a cell composition and formation of a microvascular structure. Forming human microvascular structure in vitro and

in vivo differ at least in method steps, reagents and/or dosages used, response variables, and criteria for success. Thus, they require separate search and deemed patentably distinct.

Groups I-II and group III are distinct from each other because they are drawn to different methods that differ at least in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. They have different classifications and require separate search. Thus, groups I-II and group III are patentably distinct from each other.

Groups IV-VI are distinct from each other because they are drawn to different scientific considerations: Pathology of atherosclerosis, tumor and wound healing differ from each other, therefore, treating those diseases require separate considerations. They are methods that differ at least in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. Thus, groups IV-VI are patentably distinct from each other.

Groups I-II, group III and groups IV-VI are distinct from each other because they are drawn to materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages, schedules used, response variables, and criteria for success. They have different classifications and require separate search. Thus, groups I-II, group III and groups IV-VI are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

